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TESTIMONY SUBMITTED TO THE CT LEGISLATURE'S PUBLIC HEALTH COMMITTEE

FROM: Linda Wallace, Executive Director, the Connecticut Epilepsy Foundation of CT for the Public Health Committee's Public Hearing, March 12, 2008

RE: In Rebuttal to Other Hearing Testimony

AMERICAN ACADEMY OF NEUROLOGY

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POSITION STATEMENT ON THE COVERAGE OF ANTICONVULSANT DRUGS FOR THE TREATMENT OF EPILEPSY NOVEMBER 2006

The American Academy of Neurology (AAN), representing over 19,000 neurologists and neuroscience professionals, has taken an active interest in the clinical, ethical and policy considerations concerning the coverage of anticonvulsant drugs for people with epilepsy. The AAN has developed evidence-based guidelines which strongly support complete physician autonomy in determining the appropriate use of anticonvulsants for their patients with epilepsy. Based on this evidence, the AAN has adopted the following principles concerning coverage of anticonvulsants for adults and children with epilepsy.

The AAN opposes generic substitution of anticonvulsant drugs for the treatment of epilepsy without the attending physician's approval. The FDA has allowed for significant differences between name-brand and generic drugs. This variation can be highly problematic for patients with epilepsy. Even minor differences in the composition of generic and name-brand anticonvulsant drugs for the treatment of epilepsy can result in breakthrough seizures.

- Anticonvulsant drugs for the treatment of epilepsy differ from other classes of drugs in several ways that make generic substitution problematic.

- For anticonvulsant drugs, small variations in concentrations between name-brands and their generic equivalents can cause toxic effects and/or seizures when taken by patents with epilepsy.

- The AAN opposes all state and federal legislation that would impede the ability of physicians to determine which anticonvulsant drugs to prescribe for the treatment of patients with epilepsy.

- The AAN believes that formulary policies should recognize and should support complete physician autonomy in prescribing, and patients in accessing, the full range of anticonvulsants for epilepsy.

- The AAN opposes policies that would result in arbitrary switching among anticonvulsants. Therefore, the AAN opposes generic substitution of anticonvulsants for patients with epilepsy at the point of sale (e.g., in the pharmacy), without prior consent of the physician and the patient.

- The AAN supports legislation that would require informed consent of physicians and patients before generic substitutions of anticonvulsants are made at the point of sale.

- The AAN believes that the use of anticonvulsant drugs in the treatment of epilepsy should be distinguished from the use of anticonvulsant drugs in treating other disorders. The AAN recognizes that different strategies may be appropriate in using anticonvulsants for the treatment of conditions other than epilepsy.

- Unlike other diseases, a single breakthrough seizure due to change in delivered medication dose can have devastating consequences, including loss of driver's license, injury, and even death.

The AAN supports the use of newer-generation anticonvulsant drugs in the treatment of epilepsy. Newer generation anticonvulsant drugs generally result in fewer and less-severe side-effects, although they may be more expensive to prescribe. For patients with epilepsy, the AAN does not believe that economic considerations alone should determine the prescribing pattern of physicians. The AAN believes that physicians should make every effort to identify when patients may be effectively treated with less expensive alternatives. However, the discretion for this decision should remain with the prescribing physician and should not be determined by coverage limitations.

- Physicians should have prescribing access to all anticonvulsants for the treatment of epilepsy, including newer-generation drugs.

- The AAN recognizes that, unlike in most other conditions, requiring the "fail first" approach (i.e., using trial and error in determining the best treatment option) will put patients with epilepsy at risk for breakthrough seizures, accidents, injury and loss of income.

- The AAN believes that preventing access to newer-generation anticonvulsants for the treatment of epilepsy is not cost effective in the long term. Newer drugs may have less tendency to produce some of the side effects associated with older medications, including osteoporosis, cognitive impairment, sedative impairment and depression, all of which require costly medical interventions.

- The AAN opposes cost-based strategies such as high co-pays on newer generation AEDs that effectively limit therapy options for lower-income patients.

The AAN opposes prior authorization requirements by public and private formularies. Prior authorization (i.e., requiring a physician to seek approval to prescribe a drug before the drug may be dispensed) is one method formularies may utilize to limit access to anticonvulsant drugs for the treatment of epilepsy.

- The AAN opposes prior authorization for anticonvulsant drugs in the treatment of epilepsy.

- Prior authorization impedes patient access to quality care and places an unnecessary and costly administrative burden on physicians.

- Prior authorization may affect compliance among patients with epilepsy, creating additional barriers that discourage them from seeking appropriate medication that will prevent future seizures.

Ensuring appropriate coverage of anticonvulsant drugs for the treatment of epilepsy contributes to ethical, high-quality neurological care. The AAN is pleased to serve as a resource for healthcare professionals, policy makers, and the public on this important issue.

References

American Medical Association. AMA Policy H-115.974 Prescription Labeling
American Medical Association. AMA Policy H-125.984 Generic Drugs
American Medical Association. AMA Policy H-125.993 Legislation Prohibiting Therapeutic Substitution
French JA, Kanner AM, Bautista, J et al., "Efficacy and tolerability of the new antiepileptic drugs I: Treatment of new onset epilepsy; Efficacy and tolerability of the new antiepileptic drugs II; Treatment of refractory epilepsy"; Reports of the Therapeutics and Technology Assessment Subcommittee and Quality Standards Subcommittee of the American Academy of Neurology and the American Epilepsy Society; Special Article; *Neurology* 2004;62:1252-1260.

Approved:
AAN Executive Committee ~ November 2, 2006 (Policy 2006-72)

Potential Complications of Substitution: Seizures and Toxicity

Physician Surveys on Generic Substitution

Location (Reference)	Seizure Activity or Toxicity After Generic Substitution
UK[1]	29% increase in seizures or toxicity 11% validated; 10% unproven
Canada[2]	14% reported having problems
USA[3]	**Brand-to-Generic** 68% reported breakthrough seizures 56% reported increased adverse events **Generic-to-Generic** 33% reported breakthrough seizures 27% reported increased adverse events
Multinational[4]	23% attributed breakthrough seizures to generic medication
USA[5]	65% of physicians reported having a patient experience breakthrough seizures 35% of patients thought substitution is linked to breakthrough seizures

1. Crawford P, et al. *Seizure*. 1996;5:1-5; 2. Guberman A, Corman C. *Can J Neurol Sci*. 2000;27:37-43; 3. Wilner AN. *Epilepsy Behav*. 2004;5:995-998; 4. Haskins LS, et al. *Epilepsy Behav*. 2005;:98-105; 5. Berg MJ, Gross RA. Abstract presented at: American Epilepsy Society 60th Annual Meeting; December 1-5, 2006; San Diego, CA.